GE Healthcare Surgery

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Certified Mail Return Receipt Requested

IMPORTANT- ELECTRONIC PRODUCT RADIATION WARNING

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 12, 2008

To: Director/Manager of Radiology
Facility Administrator

Subject: Product Safety Issues

Affected Product: GEHC OEC® 9800 ESP-15 C-arm & GEHC OEC® 9900 ESP-15 Elite C-arm

Our records indicate that your facility has one or more of the following GEHC OEC products:

- **GEHC OEC® 9800 ESP-15 C-arm**
- **GEHC OEC® 9900 ESP-15 Elite C-arm**

GE Healthcare Surgery has identified a potential safety issue with the systems listed above.

If your facility is receiving this notification, our records indicate that your GEHC OEC®9800 ESP-15 or GEHC OEC® 9900 ESP-15 Elite may be affected this issue.

1) GE Healthcare has discovered that the Air Kerma Rate displayed value and cumulative air kerma displayed value could exceed the allowable error under certain imaging conditions.

   The displayed value could exceed the allowable 35% error per 1020.32(k)(6) due to a calculation error ONLY when the operator has selected pulsed fluoro at 15 pulses per second, with manual technique control mode selected using extreme and unusual settings of very high kVp values in combination with very low mA values.

   The calculations are correct when operating in automatic technique control mode and in manual technique mode with usual and normal technique settings.

2) The hazard associated with this condition is that the system may record an incorrect radiation exposure value for the patient.

Interim Solution:
When operating the OEC 9800 ESP-15 or OEC 9900 ESP-15 Elite C-arm in Pulsed Fluoro Mode at 15 pulses per second, avoid the use of manual technique control mode using mA settings below 1.5 mA in combination with kVp values above 100 kVp to avoid error in the displayed values of Air Kerma and cumulative Air Kerma.

Note:
Some ESP customers received a communication dated July 6, 2007 indicating that a software correction to address this issue was being evaluated. After completion of the evaluation GEHC has concluded that this issue is best addressed by executing the removal of the 15 Pulse per Second (PPS) configuration on all 9800 ESP-15 and 9900 ESP-15 C-Arms. The removal of the 15 PPS feature will be facilitated with a software change.

A GE Healthcare Field Service Engineer (or representative) will contact your facility in order to coordinate this activity at no charge

If you have any questions or concerns regarding these issues, please do not hesitate to contact GE Healthcare Customer Service. For US Customers please contact GE Healthcare Customer Service at 1-800-874-7378 or 1-801-536-4688 as we are available 24/7.

We apologize for any inconvenience and thank you for your attention.

Thank you,

Pete McCabe
President and CEO
GE Healthcare Surgery

Maria Frame
Vice President
Quality and Regulatory Affairs
GE Healthcare Surgery